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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,064	08/23/2006	Niza Frenkel	27225U	9516

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EXAMINER	
MONTANARI, DAVID A	
ART UNIT	PAPER NUMBER
1632	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/567,064	FRENKEL, NIZA	
	Examiner	Art Unit	
	DAVID A. MONTANARI	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 February 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *72,73 and 76-106* is/are pending in the application.

4a) Of the above claim(s) *89-105* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *72, 73, 76-88 and 106* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's arguments and amendments filed on 2/4/2011 have been entered.

2. Claim 72 is amended.

3. Claim 106 is new.

4. Claim 88 has the status identifier "Currently Amended", however this should be changed to "Previously Presented".

5. Claims 72, 73, 76-88 and 106 are examined in the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 72, 73, 76-88 and 106 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicant has amended claim 72 to recite that the claimed vector is now "being configured for administration as a vaccine". Applicant states that support can be found throughout the specification. However a search of the instantly filed specification provides no support or teaching wherein the vector of claim 72 is configured for administration as a vaccine. The specification already teaches the vector of claim 72 (see Figure 1 and Example 1 for

demonstration), and provides no teachings regarding what configuration of the vector of claim 72 would result in said vector to now be designated a vaccine. If Applicant believes this rejection is in error then Applicant is invited to cite line and page number of the specification wherein the vector of claim 72 is further configured for administration as a vaccine.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 72, 73, 76-88 and 106 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 72 now recites that the claimed vector is now "being configured for administration as a vaccine". However it is unclear how the vector of claim 72 can or is configured as a vaccine. The vector of claim 72 could already serve as a vaccine on its own since it is capable of inducing an immune response, thus it is not known nor taught in the specification what configuration occurs to the vector of claim 72 to confer a status as only a vaccine.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 72, 73 and 76-88 remain rejected and claim 106 is newly rejected under 35 U.S.C. 102(b) as being anticipated by Frenkel N. (PCT/US94/12715, published 18-May 1995) for reasons of record in the Non-Final Office Action mailed on 8/4/2010 (and repeated below).

Regarding claim 72, Frenkel teaches that the vector can comprise a Tamplicon sequence, which is a DNA sequence derived from HHV-6 or HHV-7 (pg. 9 lines 20-29) and that said vector comprises an origin of replication, cleavage and packaging signal and promoter, this is taught at pg. 7 lines 10-14. The Tamplicon-7 sequence of the pending claims is the same as the tamplicon sequence taught by Frenkel since both are derived from HHV-7 and further comprises the same pac sites (see Fig. 4 of Frenkel and Figs. 1 and 2 of the instant invention.

Regarding the method of vaccination of new claim 106 and the limitation wherein said vector is "configured for administration as a vaccine", Frenkel teaches that their vector is useful for the prophylaxis of lymphomas or various auto-immune diseases or disorders (pg. 9 lines 1-3). Accordingly the vector taught by Frenkel is inherently configured as a vaccine since it can provide prophylaxis and already is capable of inducing an immune response.

Regarding claim 73, Frenkel teaches that the claimed vector will form concatemers (pg. 4 lines 14-18).

Regarding claim 76, Frenkel teaches that the vector is packaged in a virion particle (pg. 20 lines 8-13).

Regarding claim 77, Frenkel teaches that HHV-6 expression leads to exanthem subitum, which is an immune response to HHV-6 protein expression (pg. 3 lines 32-34).

Regarding claims 78 and 81, Frenkel teaches that the vector of the claimed invention can comprise a foreign nucleic acid sequence such as a detectable marker (pg. 13 lines 2-5).

Regarding claims 79 and 80, Frenkel teaches that the foreign nucleic acid sequence can be targeted to the cell membrane (pg. 14 lines 3-14) or secreted out of the cell (pg. 14 lines 15-21) where the production of insulin or enzymes are used to treat diseases associated with their deficiencies.

Regarding claims 82 and 106, Frenkel teaches that their claimed vector is "useful as an agent for genetic therapy in the treatment of various malignancies, viral infections, enzyme deficiencies and others, of lymphatic cells as well as other cells capable of being infected with HHV-6 or HHV-7" (pg. 9 lines 15-18).

Regarding claims 83, 84 and 88, Frenkel teaches that a helper virus will be provided along with the claim vector to assist in the replication of the Tamplicon (pg. 9 lines 22-24) and that a cell will comprise the helper virus (pg. 23 lines19-21).

Regarding claims 85, 86 and 87, Frenkel teaches that the vector of the invention may also be used for infection of lymphocytes ex vivo and then returned to a patient (pg. 16 lines 3-4), wherein the vector comprises a foreign nucleic acid sequence (pg. 7 lines 15-22). Further it is art accepted that lymphocytes comprise B and T cells and thus the lymphocytes infected by the vector taught by Frenkel would encompass the B and T cells of claim 87.

Response to Arguments

Applicant's Arguments

Applicants argue in amendment filed on 2/4/2011 that Frenkel et al. does not teach every limitation of the claimed invention. Specifically Applicant's argue that Frenkel describes the administration of HHV-6 or HHV-7 as lymphotropic vectors for delivering DNA into lymphocytes which is defined by Frenkel as providing "lymphotropic agents, i.e. agents capable

of exerting therapeutic effects on lymphatic cells." Applicants continue that Frenkel describes the agents exerting therapeutic effects on lymphatic cells, which is based on the ability of HHV-6 and HHV-7 to bind to the T cell marker, CD4.

Applicants continue that Frenkel teaches a vector including HHV-6 or HHV-7 sequences and optionally a foreign nucleic acid, however nowhere in the cited reference does Frenkel teach to the claimed vector being configured for administration as a vaccination.

Examiner's Response

While Applicant has amended claim 72 to recite that the claimed vector is now configured for administration as a vaccine, this limitation does not overcome the instant 102(b) rejection. The vector of claim 72 is already capable of inducing an immune response upon administration, as required by line 8 of claim 72. As discussed in the New Matter rejection above, the instant specification provides no definition or examples of how the vector of claim 72 is configured for administration as a vaccine. This function of the claimed vector as well as the vector taught by Frenkel already serves the requirement that the vector act as a vaccine.

Additionally, the terms prophylactic and vaccine as defined in the art would support that the vector of claim 72 can already serve as a vaccine. For example Steadman's Medical Dictionary (22nd Edition) defines,

prophylactic as:

"1. Preventing disease; relating to prophylaxis.

2. An agent, e.g. diptheria toxoid, typhoid vaccine, etc., that acts to as a preventative against any disease."

vaccine as:

"1. The live vaccine (vaccinia, cowpox) virus inoculated in the skin as prophylaxis agains smallpox, and obtained from the skin of calves inoculated with seed virus.

2. Any microbial preparation used for active prophylaxis; these v.'s are of two chief kinds, (a) those inactivated by heat or chemical agents , and (b) live, attenuated agents.

3. Any material, including toxoids, used for active prophylaxis."

As taught by Steadman's Med. Dict. Above, any material can be used for active prophylaxis of which the vector recited in claim 72, which is capable of inducing an immune response, will in fact serve as a prophylactic upon administration. As recited in the 112 2nd above, the specification does not teach how the claimed vector is "configured" to serve as a vaccine and thus it is not know how this configuration imparts any additional or structral limitations on the claimed vector that would distinguish it from the vector taught by Frenkel which can serve as a prophylactic.

The specification provides no additional teaching or guidance that would distinguish the vector of claim 72 as vaccine, either by function or structure, from the vector taught by Frenkel. As the 102(b) is amended above to address new claim 106 and the instant claim amendments, Frenkel taught at the time of filing that their vector would be useful for the prophylaxis of lymphomas and various auto-immune diseases, thus the vector of Frenkel would inherently be configured for the administration as a vaccine since it could provide prophylaxis.

Thus for the reasons above and of record the rejection is maintained.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID A. MONTANARI whose telephone number is (571)272-3108. The examiner can normally be reached on M-Tr 8-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 1-571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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